

§ 807.25

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of whether any changes were made to the owner or operator's list of devices; and

(4) Changes to listing information may also be made at other times, such as when a device is introduced into commercial distribution, when a change is made to a previously-listed device, or when a previously-listed device is removed from commercial distribution.

(c) *Failure to submit required information.* Failure to submit any of the required information on time, as specified in paragraphs (a) and (b) of this section, will put the establishment in a "failed to register" or "failed to list" status as applicable. The establishment will not be considered active and the establishment registration and device listing information may not appear on the FDA Web site until such time as the owner or operator submits and FDA processes the required information.

[77 FR 45942, Aug. 2, 2012]

§ 807.25 Information required for device establishment registration and device listing.

(a) All owners or operators that are subject to the registration and listing requirements of this part shall provide such information to us by using the FDA electronic device registration and listing system, unless granted a waiver from electronic submission in accordance with § 807.21(b). Electronic submissions of registration and listing information must comply with part 11 of this chapter, except for the requirements in § 11.10(b), (c), and (e), and the corresponding requirements in § 11.30 of this chapter. Those owners or operators granted a waiver from electronic submission should refer to paragraphs (c) and (g) of this section and § 807.34 for instructions on how to submit device registration and listing information.

(b) Registration information required to be submitted includes: The name and mailing address of the device establishment; the Web site address of the device establishment, if any; the name, address, phone number, fax number, and email address of the owner or operator; the name, address, phone number, fax number, and email address

of the establishment's official correspondent; and all trade names used by the establishment.

(c) Owners or operators who have been granted a waiver from electronic filing must submit the establishment registration information described in paragraph (b) of this section, except for the Web site and email address information, in paper form using the procedures set forth in § 807.34.

(d) Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment registered by the owner or operator and to furnish this information to FDA upon request.

(e) For each establishment, an official correspondent must be designated by the owner or operator to serve as a point of contact with FDA on matters relating to the registration of device establishments and the listing of device products. Each owner or operator shall also provide FDA with the name of a contact person at the owner or operator's offices who will be responsible for identifying the official correspondent for each establishment. The owner or operator contact person will be the official correspondent in the event no one else has been properly designated. The official correspondent is responsible for:

(1) Providing FDA with all required registration and listing information electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b);

(2) Receiving all correspondence from FDA concerning registration and listing;

(3) Supplying, when requested by FDA, the names of all officers, directors, and partners; and

(4) Receiving communications from FDA by email, or by postal mail if the owner or operator has been granted a waiver from the requirement to file registration and listing information electronically.

(f) The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under section 301(p) or any other provision of the Federal Food, Drug, and Cosmetic Act.

(g) Device listing information must be submitted to FDA electronically unless a waiver from electronic submission has been granted in accordance with § 807.21(b). Owners or operators who have been granted a waiver must submit the required device listing information, including information required by this paragraph, § 807.28, and any listing information requested by FDA under § 807.26(e), in paper form using the procedures set forth in § 807.34. The information required for each device listed includes:

(1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed.

(2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976.

(3) The proprietary or brand name(s) under which each device is marketed.

(4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, granted de novo classification petition, or approved humanitarian device exemption for each device listed that is subject to sections 505, 510(k), 513(f)(2), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, which includes devices that are not exempt from premarket notification and approval.

(5) Each activity or process that is conducted on or done to the device at each establishment, such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only.

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§ 807.26 Additional listing information.

(a) Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:

(1) For each device subject to section 514 or 515 of the act that is not a restricted device, a copy of all labeling for the device;

(2) For each restricted device, a copy of all labeling and advertisements for the device;

(3) For each device that is neither restricted nor subject to section 514 or 515 of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.

(b) In addition to the requirements set forth in paragraph (a) of this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made anytime after initial listing.

(c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discontinued device by an owner or operator.

(d) Location of the file:

(1) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner.

(2) The contents of the historical file may be physically located in more than one place in the establishment or in more than one establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Food and Drug Administration with a letter authorizing the establishment outside its control to maintain the historical file.

(3) A copy of the certification and disclosure statements as required by part 54 of this chapter shall be retained and physically located at the establishment maintaining the historical file.

(e) Each owner or operator shall be prepared to submit to the Food and Drug Administration, only upon specific request, the following information:

(1) For a device subject to section 514 or 515 of the act that is not a restricted